

1 1. In a medical or orthodontic component or device having at least a
2 portion thereof fabricated from Ni-Ti based shape memory alloy, the
3 improvement comprising:

4 (a) said alloy being more than 50 atomic % nickel;

5 (b) said alloy having been solution treated at a temperature of 650 to 1100° C. for
6 10-60 minutes;

7 (c) after cooling, said alloy having been aged by heating it at a temperature of
8 approximately 350° C. for 10-60 minutes;

9 (d) said portion being characterized by:

10 (i) having pseudoelastic properties without cold working,

11 (ii) having greater than 2.5% elasticity over a temperature range of -20° C.
12 to +40° C., and

13 (iii) allowing large plastic deformations during the fabrication of said
14 portion.

1 2. A component or device as defined in claim 1, characterized by being capable
2 of large amounts of cold forming without danger of cracking or fracture during
3 forming operations in its solution treated condition which are required to make
4 orthodontic and medical components.

1 3. A component or device as defined in claim 2 wherein said portion is an
2 orthodontic component.

1 4. A component or device as defined in claim 2 wherein said portion is a stent.

1 5. A component or device as defined in claim 2 wherein said portion is at least
2 one selected from the group consisting of: a catheter introducer; oral maxillofacial
3 reconstructive procedures using pins and/or plates; an oviduct clamp; a bone
4 staple; a graft prosthesis; a stent for biliary, urinary or vascular system; an infusion
5 catheter; and a urological stent.

1 6. A component or device as defined in claim 2, wherein said alloy
2 composition is about 56.1wt% NI-43.9%Ti, which is solution treated at a
3 temperature of 850° C. and subsequently water quenched and which can be readily
4 cold formed in this condition, and which is subsequently aged at 350° C. generates
5 pseudoelastic behavior in the component which is observed over the temperature
6 range of -20° to +40° C.

1 7. A component or device as defined in claim 6, wherein said portion has been
2 solution treated for about 30 minutes, and has been aged for about 30 minutes.

1 8. A component or device as defined in claim 7 wherein said portion has been
2 cold worked about 20% before the solution treatment whereby the temperature
3 range of the pseudoelastic performance is extended.

1 9. A component or device as defined in claim 7, wherein the relatively small
2 amounts of cold work before the ageing treatment do not exceed 30%.

1 10. A component or device as defined in claim 2 wherein said portion is further
2 characterized by a pseudoelastic or superelastic behaviour over the temperature
3 range from -20°C to +40°C.

1 ~~11.~~ A component or device as defined in claim 1, wherein said alloy portion has
2 additional alloying elements, which, without substantially altering the processing
3 of the portion, extend the temperature range of the pseudoelastic behaviour of the
4 portion, and wherein said additional alloying elements are at least one selected
5 from the group consisting of Ta, Mo, Nb, Co, Cr, Cu, V, Mn and Fe.

1 ~~12.~~ A component or device as defined in claim 10 wherein the shape memory
2 portion exhibits pseudoelastic properties with an upper plateau stress which is
3 between approximately 42Ksi and 72Ksi, whereby the stress level is well suited for
4 orthodontic and medical components.

1 ~~13.~~ A component or device as defined in claim 10 wherein there has been cold
2 work of about 10-15% either before or after aging treatment and this has little effect
3 on the pseudoelastic properties except for a slight improvement in this property.

1 ~~14.~~ A component or device as defined in claim 10 wherein the aging treatment
2 has provided stress relief after secondary operations such as coating, plating or
3 joining while at the same time imparting the desired pseudoelastic properties.

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1 15. A component or device as defined in claim 10 characterized by the portion
2 having been subjected to various cold work levels during fabrication to create
3 various cross section of the design and after aging treatment exhibiting
4 substantially uniform pseudoelastic properties.

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1 16. A component or device as defined in claim 10 which exhibits
2 pseudoelasticity at ambient and/or body temperature.

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1 17. A component or device as defined in claim 10 wherein said portion is one
2 selected from the group consisting of orthodontic arch wire, springs, implants,
3 endodontic files.

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1 18. A component or device as defined in claim 10 wherein said portion is
2 characterized by having super-elastic properties by having been solution treated
3 and aged, and exhibiting complete elastic behavior at strains up to 4%, thereby
4 permitting the designing of medical instruments and devices which are resistant
5 to permanent deformation or kinking.

1 19. A method of making at least a component of a medical or orthodontal
2 instrument or device, comprising:

3 (a) fabricating said component of an alloy which includes

4 (i) an alloy of NiTi with a higher nickel content than an equiatomic Ni/Ti
5 ratio in a Ni-Ti shape memory alloy,

6 (ii) and which has been solution treated at a temperature of 650 to 1100° C.

7 for 10-60 minutes; and

8 (b) aging said component after it is fabricated, by heating it at a temperature of
9 approximately 350° C. for 10-60 minutes,

10 said portion being characterized by:

11 having pseudoelastic properties without cold working,

12 having greater than 2.5% elasticity over a temperature range of -20° C. to

13 +40° C., and

14 allowing large plastic deformations during the fabrication step before the desired

15 pseudoelastic properties are established.

1 20. A method as defined in claim 19, wherein said step of fabricating includes
2 large plastic deformations of said alloy before pseudoelasticity is imparted to the
3 component.

1 21. A method as defined in claim 20, wherein said NiTi based shape memory
2 component is characterised by having pseudoelastic properties without using cold
3 working and greater than 2.5% elasticity over the temperature range of -20 to +40°
4 C.

1 22. A method as defined in claim 19, wherein said component is formed into
2 an orthodontic arch wire.

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1 24. A method as defined in claim 19, wherein said component is formed into
2 an a medical device for use within a living body.

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1 25. A method as defined in claim 19, wherein said component is formed into a
2 medical device chosed from the group consisting of: (1) a stent; (2) a catheter
3 introducer; (3) oral poins and/or plates used in maxillofacial reconstructive
4 procedures; (4) an oviduct clamp; and (5) bone staples.

MEM P82 v2.2 5/17/99